JUL 14 2003

k031183

# 510(k) SUMMARY

**SPONSOR NAME:** Centerpulse Orthopedics, Inc.
9900 Spectrum Drive
Austin, TX 78717

**510(k) CONTACT:** Robert M. Wolfarth
Phone: (512) 432-9324
Robert.Wolfarth@Centerpulse.com

**TRADE NAME:** Tibial Spacer for the Natural-Knee® II Cemented Modular Tibial Baseplate

**COMMON NAME:** Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis

**CLASSIFICATION:** Knee joint femorotibial metal/polymer semi-constrained cemented prostheses (Product Code 87 HRY) are Class II per 21 CFR §888.3530, reviewed by the Orthopedic Devices panel.

**PREDICATE DEVICE:**
The new Tibial Spacer is substantially equivalent to the Centerpulse Orthopedics Natural-Knee® System Tibial Spacer.

**DEVICE DESCRIPTION:**
These Tibial Spacers are optional components designed to mate with the previously-cleared Natural-Knee® II Cemented Modular Tibial Baseplate. Like the Tibial Baseplate, the Tibial Spacers are manufactured from cobalt chrome alloy. The tibial spacers are available in seven sizes (00 through 5) and in two thickness levels. They are available in both medial and lateral and both left and right configurations to match the radial contour of the baseplates.

**INTENDED USE:**
The Tibial Spacer is a primary component intended for cemented use only in total knee arthroplasty in skeletally mature individuals for treatment of the following:

- Patient conditions of Noninflammatory Degenerative Joint Disease (NIDJD); e.g., avascular necrosis, osteoarthritis and Inflammatory Joint Disease (IJD); e.g., rheumatoid arthritis;
- Correctable valgus-varus deformity and moderate flexion contracture.
- Those patients with failed previous surgery where pain, deformity, or dysfunction persists.

**BASIS OF SUBSTANTIAL EQUIVALENCE:**
Performance testing, design comparisons, and functional analyses conducted on Tibial Spacers for the Natural-Knee® II Cemented Modular Tibial Baseplate demonstrate that the Tibial Spacer is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 2003

Mr. Robert M. Wolfarth
Regulatory Affairs Programs Manager
Centerpulse Orthopedics, Inc.
9900 Spectrum Drive
Austin, Texas 78717

Re: K031183
Trade/Device Name: Tibial Spacer for the Natural-Knee® II Cemented Modular Tibial Baseplate
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: April 14, 2003
Received: April 15, 2003

Dear Mr. Wolfarth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications For Use

*510(K) Number*: K031183

*Device Name*: Tibial Spacer for the Natural-Knee® II Cemented Modular Tibial Baseplate

*Indications for Use*:

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- Correctable valgus-varus deformity and moderate flexion contracture.
- Those patients with failed previous surgery where pain, deformity, or dysfunction persists.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031183